

embolic stroke mechanism, including those with superficial vascular distribution, convexity strokes, and strokes of larger size, providing additional evidence of a biological effect of closure with the AMPLATZER PFO Occluder.

Intraoperative CT-Guided Endoscopic Surgery for ICH [ICES]

Written by Phil Vinal

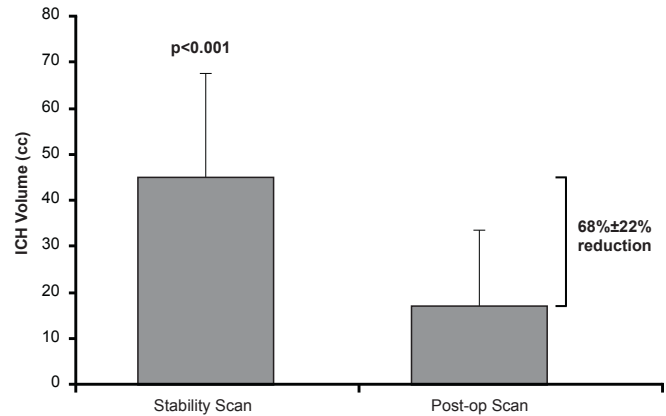
Paul Vespa, MD, University of California, Los Angeles, Los Angeles, California, USA, presented 180-day data from the Intraoperative CT-Guided Endoscopic Surgery trial [ICES] showing that early CT-guided endoscopic surgery is safe and associated with improved neurological outcomes compared with medical management in patients with primary intracerebral hemorrhage (ICH).

ICES is a substudy of the Minimally Invasive Surgery Plus rtPA for Intracerebral Hemorrhage Evacuation study [MISTIE; NCT00224770]. The inclusion and exclusion criteria for ICES were the same as for MISTIE to facilitate a prespecified comparison between ICES surgery and the combined ICES plus MISTIE medical control arm. Randomization and surgery took place within 48 hours of stroke onset. Two serial CT scans were performed ≥ 6 hours apart to ensure that the hematoma remained stable. The ICH volume threshold was >20 cc; some intraventricular hemorrhage was permitted.

Surgery was accomplished using a stereotactic navigational scan. The endoscope was inserted two thirds of the way into the hematoma along its long axis, and suction and then irrigation were applied for variable amounts of time. The endoscope was backed off to about one third of the depth, and suction and irrigation were repeated before the instrument was withdrawn. A postoperative CT scan was performed. The primary study endpoint was safety. Secondary endpoints included volume reduction, surgical serious adverse events, and modified Rankin Scale (mRS) score at 180 and 365 days.

Subjects (mean age, ~ 62 years; mostly men) were randomly assigned to endoscopic surgery ($n=18$) or medical management ($n=6$). Mean time to surgery was 32.8 ± 14 hours. Endoscopic surgery resulted in a $68\% \pm 22\%$ immediate volume reduction ($p < 0.001$; Figure 1) with the volume being reduced to <15 cc in 67% of patients. Volume was unchanged in the medically managed patients after 72 hours. Mortality at 7, 30, and 180 days post onset was significantly higher in the medical (0%, 7%, and 60%, respectively) versus the surgical arm (0%, 4%, and 13%, respectively; $p < 0.01$). One surgical patient had immediate nonfatal postoperative rebleeding. There was no immediate surgical-related mortality.

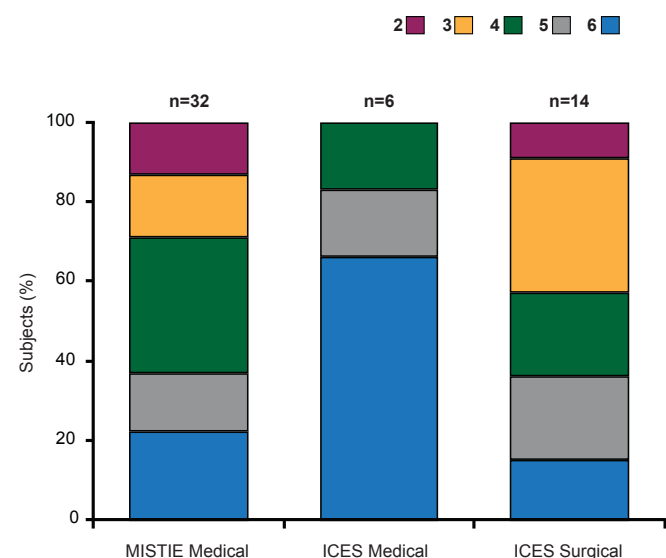
Figure 1. Volume Reduction



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At 180 days, good neurological outcome (mRS score 0 to 3) was more frequent in patients receiving surgery (45%) compared with those on medical therapy (0%; Figure 2). On a prespecified intention-to-treat secondary analysis of ICES surgery versus combined medical controls in ICES plus MISTIE ($n=13$ vs $n=36$) at 180 days, the proportion of mRS scores 0 to 3 remained 15% greater in ICES surgery versus combined medical controls (38% vs 23%) [Vespa P et al. ISC 2013 (abstr LB2)].

Figure 2. Functional Outcomes: mRS at Day 180



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CLINICAL TRIAL HIGHLIGHTS

Dr. Vespa noted that endoscopic surgery for ICH is safe (eg, lower mortality at all time points compared with medical treatment), results in an immediate 70% reduction in ICH volume, and conveys a 15% advantage for a good clinical outcome (mRS score ≤ 3) after 180 days. Despite some variability in surgical technique—particularly with respect to suction, the procedure is generalizable and reproducible across multiple centers and surgeons.

The EMBRACE Trial: Prolonged Ambulatory Cardiac Monitoring Improves the Detection and Treatment of Atrial Fibrillation in Patients With Cryptogenic Stroke

Written by Phil Vinal

Data from the 30-Day Cardiac Event Monitor Belt for Recording Atrial Fibrillation After a Cerebral Ischemic Event trial [EMBRACE; NCT00846924] presented by David J. Gladstone, MD, PhD, University of Toronto, Toronto, Ontario, Canada, showed that prolonged continuous cardiac monitoring to detect poststroke paroxysmal atrial fibrillation (AF) in patients with unexplained strokes is feasible, more effective than standard approaches, and leads to clinically meaningful changes in patient management.

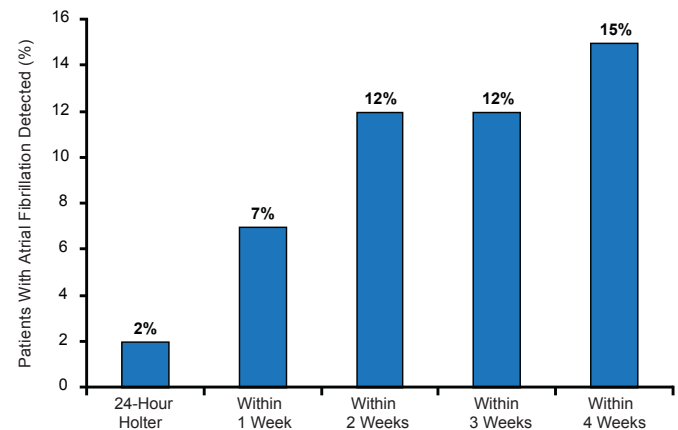
Identification and treatment of AF can prevent second strokes; however, paroxysmal AF can be difficult to detect in patients with stroke or transient ischemic attack (TIA), and the most common screening method, 24-hour Holter monitoring, has a low sensitivity (~5%) for detecting it post stroke. Small observational studies have suggested benefits of longer duration electrocardiogram (ECG) monitoring [Stahrenberg R et al. *Stroke* 2010; Sobocinski PD et al. *Europace* 2012; Flint AC et al. *Stroke* 2012]. The objective of the EMBRACE study, funded by the Canadian Stroke Network, was to determine the diagnostic yield of 30 days of home-based cardiac monitoring compared with repeat 24-hour Holter monitoring for detecting paroxysmal AF in patients with a recent diagnosis of cryptogenic ischemic stroke or TIA following a routine diagnostic stroke workup that included a negative Holter monitor. Secondary outcomes included monitoring adherence and anticoagulation status.

To be eligible for the study, patients had to be aged ≥ 55 years without previously documented AF, with a recent (≤ 6 months) diagnosis of a presumed embolic acute arterial ischemic stroke (confirmed by neuroimaging) or TIA of etiology (or suspected cardioembolic etiology but without proven AF). Subjects were required to

have negative results on baseline tests that included ECG, Holter monitor, vascular imaging with computed tomography angiography or magnetic resonance angiography, and echocardiography. The primary study outcome was detection of ≥ 1 episode of AF or atrial flutter of ≥ 30 seconds within 90 days of randomization, confirmed by central adjudication. The study included 572 subjects (mean age, 73 years; ~45% women). Sixty-three percent of the subjects had an ischemic stroke and 37% had a TIA. Baseline anticoagulant use was 5%. Over 90% of participants had a modified Rankin score of 0 to 2, indicating functional independence. Subjects were randomly assigned to repeat 24-hour Holter monitoring (n=285) or 30-day cardiac monitoring (n=287). In the 30-day group, subjects wore an event-triggered loop recorder (attached to a nonadhesive chest electrode belt) that was programmed to automatically record AF. They were instructed to wear this recorder for as much of the day as possible for up to 30 days or until AF was detected. The median number of days from the index event to randomization was about 70 (range, 45 to 103).

New AF was detected in significantly more patients in the 30-day group (16%) compared with the repeat Holter group (3%; $p < 0.001$; Table 1). In the 30-day group, 82% of all participants wore their monitor for ≥ 3 weeks. Most AF events were captured within the first 2 weeks, with an incremental yield up to 30 days (Figure 1). Most patients with newly detected AF (72%) were placed on anticoagulants. Anticoagulant use increased by 90 days and was significantly greater in the 30-day group (18%) compared with the repeat Holter group (10%; $p = 0.01$; Table 2).

Figure 1. Time to First Atrial Fibrillation Detection



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